Michigan Department of Community Health

MDCH Bureau of Laboratories

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Laboratory Detection and Reporting
Carbapenem-Resistant *Enterobacteriaceae* (CRE)

- The Michigan Department of Community Health (MDCH) Bureau of Laboratories is currently doing CRE confirmatory tests on suspect CRE sent to MDCH from hospital laboratories in MI
  - Uses gold standard and DNA methods not available in clinical laboratories
  - Started January 2013
  - Funded by one-time non-renewable CDC/APHL (Association of Public Health Laboratories) grant of $50,000, which ends June 30, 2013
  - The **cost of confirmatory testing** in MDCH laboratories is estimated ~ $92.00 per patient isolate (i.e., each organism)
  - MDCH anticipates testing ~ 500 isolates
  - Testing will end Oct. 1, 2013 or sooner without additional funding
    - (estimated need = $45,000 per year)

- MDCH Laboratory results to date (Jan 2, 2013 to April 12, 2013):
  - Isolates have been received from 30 laboratories in all geographic regions of the state
  - 113 suspect isolates have been tested
  - 52 of the 113 were positive for KPC, which is the most common type of CRE resistance
  - The 52 confirmed KPC-positive CRE were received from 15 of the 30 laboratories, which are located in both rural and urban areas

NOTE: These results do not necessarily represent hospital inpatients. Many long-term care facilities send their testing to a nearby hospital laboratory

- Detection of CRE in the clinical (hospital laboratory) setting is difficult
  - The definition of CRE is not straightforward with current clinical testing methods
  - CRE currently encompasses more than a dozen species, and resistance is caused by several different mechanisms; unlike MRSA, which is one species with a single resistance mechanism
  - The accuracy of testing varies depending on the type of CRE and the testing system used
  - Automated test systems used by all hospitals require additional testing for CRE. This requires an extra 24-48 hours, and is not a billable test
  - Clinical laboratories are increasingly short-staffed and many lack the skilled microbiologists to perform the additional testing
  - Manufacturers of commercial test instruments and systems must go through rigorous FDA In-Vitro Diagnostics (IVD) approval process when new resistance appears and subsequent changes are needed in a testing method – this can take 1-2 years
  - Majority of hospital laboratories lack resources to validate in-house test performance of additional (manual or molecular) methods

- CRE confirmatory testing done at MDCH laboratory is of value and fills a proven need
- MDCH laboratory also offers training and consultation to clinical laboratories on this complex issue

The MDCH CRE confirmatory testing is performed under the direction of James Rudrik, Ph.D.(RudrikJ@michigan.gov) and is coordinated by Martha Boehme, MLS(ASCP)^{CM} (BoehmeM@michigan.gov)